K062151
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INNOVASIS, Inc.
614 East 3900 South
Salt Lake City, UT 84107
801-261-2236
Fax 801-261-0573

DEC 2 2 2006

Box™ Peek VBR System
510(k) Summary

June 5, 2006

Company: Innovasis Inc.
614 East 3900 South
Salt Lake City, UT 84107

Contact: Warren M. Dansie
Phone: (801)261-2236
Fax: (801) 261-0573

Trade Name: Box™ Peek VBR System

Common Name: Vertebral Body Replacement

Classification: Product Code: MQP
Regulation Number: 21 CRF 888.3060
Classification Name: Spinal intervertebral body fixation orthosis.
Panel code: 87

Substantially Equivalent Devices:
- K043316 – Rabea™ - Signus
- K032064 – CPOD/LPOD™ VBR System – Theken
- K050553 – Novel™ VBR Spinal System - Alphatec
- K031757 – Peek Tetris™ - Signus
- K050449 – Quantum Vertebral Body Replacement – Quantum Orthopedics

Device Description:

The Innovasis Box™ Peek VBR System consists of polyetheretherketone(peek) implants meant to be used only in pairs and with supplemental fixation. The devices are offered in a variety of different shapes (i.e. curved, rectangular) and sizes, in order to better accommodate a patient's anatomy. The implants also feature holes located throughout their geometry in order to accommodate bone graft and maximize bone ingrowth.

Tantalum markers are incorporated into the material to allow for visualization of the implant configuration during and after surgery. The ends of the implants have machined barbs meant to engage the vertebral endplates and prevent expulsion.

Performance Data: Non-clinical (Bench):
Performance testing indicates that the Box™ Peek VBR System is capable of performing in accordance with its intended use.

Materials: The implants are machined from Medical Grade peek (Polyetheretherketone) OPTIMA (Invibio™) per ASTM F2026. Marker beads machined from Tantalum per ASTM F560.

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Salt Lake City, UT 84107
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Intended Use:

Indications for use are as follows:

The Innovasis Box™ peek VBR System is a vertebral body replacement indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedures due to tumor or trauma, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

This device is intended to be used with internal supplemental spinal fixation systems such as the Innovasis Excella™ Pedicle Screw System. The interior of the Box™ system can be packed with allograft or autograft. Box™ implants are intended to be used in pairs.

Basis for Substantial Equivalence:

The Box™ Peek VBR System has been subjected to risk analysis and engineering analysis and has been shown to be substantially equivalent to the predicates:

- K043316 – Rabea™ - Signus
- K032064 – CPOD/LPOD™ VBR System – Theken
- K050553 – Novel™ VBR Spinal System - Alphatec
- K031757 – Peek Tetris™ - Signus
- K050449 – Quantum Vertebral Body Replacement – Quantum Orthopedics

with regards to indications for use, technology and performance.

Summary of Safety and Effectiveness:

The Innovasis Box™ Peek VBR System is shown to be safe and effective for use as a vertebral body replacement and in the indications associated with device product code MQP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2006

Innovasis Inc.
c/o Mr. Warren Dansie
614 East 3900 South
Salt Lake City, UT 84107

Re: K062151
Trade Name: Box™ PEEK VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 18, 2006
Received: December 19, 2006

Dear Mr. Dansie:

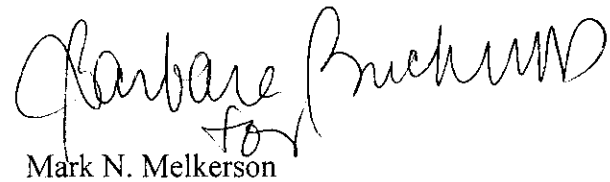
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications of Use Statement

510(k) Number: K062151

Device Name: Box™ Peek VBR System

Indications for use:

The Innovasis Box™ peek VBR System is a vertebral body replacement indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedures due to tumor or trauma, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

This device is intended to be used with internal supplemental spinal fixation systems such as the Innovasis Excella™ Pedicle Screw System. The interior of the Box™ system can be packed with allograft or autograft. Box™ implants are intended to be used in pairs.

Prescription Use _____X_____ (21 CFR 801 Subpart D) OR Over-The-Counter-Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062151